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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/563,830 | 01/25/2007 | David Bruge | 09097-8001.US00 | 5020 |
| 91106 | 7590 | 03/14/2011 | | |
| Perkins Coie LLP | | | EXAMINER | |
| 700 Thirteenth Street, NW | | | MORRIS, PATRICIA L | |
| Suite 600 | | | | |
| Washington, DC 20005-3960 | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| | | | | |
| NOTIFICATION DATE | DELIVERY MODE | | | |
| 03/14/2011 | ELECTRONIC | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/563,830 | BRUGE ET AL. |
| | Examiner | Art Unit |
| | PATRICIA MORRIS | 1625 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 January 2011.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4-6,11,15-22,24-26 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 6-8,10,11,15-22,24-26 and 28-31 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4,32 and 33 is/are rejected.
- 7) Claim(s) 9 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claims 4, 9, 32 and 33 are under consideration in this application.

Claims 6-8, 19, 11, 15-22, 24-26 and 28-31 remain held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restrictions

The restriction requirement is deemed sound and proper and is hereby made FINAL. It is noted the applicants elected without traverse in their reply on August 12, 2010.

Again, the search will not be extended because applicants have been given a very reasonable genus that is supported by the enabling disclosure in table 2. Very few compounds are even exemplified in the specification and the specification is non-enabling for many of the claimed compounds. Applicants are invited to note the anticipatory references recited on applicants' own international search report. Further, claims 6-8 are not drawn to composition claims as incorrectly alleged by applicants. Claims 6-8 are clearly improper and do **not** conform to U.S. Practice.

The request for rejoining the method claims with the elected compound cannot be made because applicants have failed to present any allowable product claims directed to the elected compounds. Moreover, it is evidenced that it is well recognized in the art that raf-kinases and VEGFR kinases are a class of enzymes involved in many regulatory mechanisms with other enzymes and physiological systems. Claim 25 is drawn to the treatment and prevention of any and all unknown disorders. There is no evidence of record that the instant compounds are able to treat and prevent all disorders associated with an alleged inhibition of a raf-kinase or VEGFR kinase. The method claims are drawn to the method of treating and preventing a staggering

laundry of disease. A claim to all raf-kinase mediated disorders is considered a reach through to the continuous development of the field and do not meet the requirements of 35 U.S.C. 112.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112**. In the instant case, none of the method claims meet the requirements of 35 U.S.C. 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the

limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Applicants are reminded of propriety of process of use claims in consideration of the "reach-through" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention. .

Again, the application has been examined to the extent readable on the elected compounds of formula IIb (R⁸ is phenyl and Ar² is pyridin-3-yl) wherein X and Y are O and R⁶-R¹⁰ represent non-heterocyclic groups as set forth in claim 32, exclusively. All additional heterocycles and heteroaryls pertain to nonelected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The plural "s" on compounds makes claims 4 and 33 read on mixtures rather than specific compounds.

The terms comprising and contains recited throughout claim 32 are open-ended.

Applicants canceled claim 1 and then re-inserted the terms in claim 32. Applicants merely allege that the terms are clear.

Contra to applicants' arguments in the instant response, one cannot tell from a simple reading of the claim what is being claimed. One must first conceive of the intended groups. Then one must, by preparing the compound himself, determine if the nitrogen protecting group works or not. Where is the specific claiming and distinctly pointing out? How can applicants regard as their invention inexact concepts? The breadth of which they could not have possibly checked out with representative exemplification. The terms are not finite.

Applicants are claiming a compound of the formula. Pure chemistry, a compound. Not a resin of general property ranges, but a pure compound. That compound used for any purpose is taken from the public in a 20-year monopoly to applicants. Then, the public is entitled to know what compound they cannot use. Yet, the claim is not specific to that compound. The public cannot tell what they may not use. How is a claim of the instant breadth defensible in an infringement action?

As applied to pure compounds, *In re Cavallito and Gray*, 134 USPQ 370, and *In re Sus and Schaefer*, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

The claims measure the invention. *United Carbon Co. V. Binney & Smith Co.*, 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations

of the specification read into a claim where no express statement of the limitation is included in the claim": *In re Priest*, 199 USPQ 11, at 15.

Allowable Subject Matter

Claim 32 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and if rewritten directed solely to the elected compounds indicated as being examinable, *supra*.

Claims 4 and 33 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims and if rewritten directed solely to the elected compounds.

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if rewritten directed solely to the elected compounds.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Patricia L. Morris/
Primary Examiner, Art Unit 1625

plm
March 9, 2011